

K210946 Promisemed Automatic Biopsy Needles, Promisemed Co-Axial Biopsy Devices, Promisemed Semi-automatic Biopsy NeedlesAug 12, 2021
135 days to decisionK210946 · Product code: **KNW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k210946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Biopsy (KNW)
Date received	Mar 30, 2021
Decision date	Aug 12, 2021
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Promisemed Hangzhou Meditech Co., Ltd.
Location	Hangzhou, CN
Contact	Zearou Yang
510(k) history	34 submissions · 34 cleared · 2017-2026

REGULATORY CONSULTANT

Consulting firm	Vee Care (Asia) Limited
Contact	Wei Shan Hsu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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